



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,219	10/24/2005	Junta Yamamichi	03500.103121.	8285
5514 7590 05/11/2010 FITZPATRICK CELLA HARPER & SCINTO 1290 Avenue of the Americas NEW YORK, NY 10104-3800				
EXAMINER				
HANDY, DWAYNE K				
ART UNIT		PAPER NUMBER		
1797				
MAIL DATE		DELIVERY MODE		
05/11/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/554,219

**Applicant(s)**

YAMAMICHI, JUNTA

**Examiner**

DWAYNE K. HANDY

**Art Unit**

1797

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7, 12 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7, 12 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 7, 12 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 35 U.S.C. 103(a) as obvious over Weigl et al. (6,454,945). This rejection was maintained in the previous Office Action (mailed 10/16/09). It remains in effect. Please see Response to Arguments below.

***Response to Arguments***

4. Applicant's arguments filed 01/19/10 have been fully considered but they are not persuasive. Applicant has argued that Weigl fails to teach or suggest using a same label for simultaneously detecting different target substances (Page 6 of Arguments

submitted 1/19). The Examiner respectfully disagrees and directs Applicant to column 37, lines 16-53 of Weigl:

(88) In the case of fluorescent reporter beads, at least one fluorescence property of the reporter molecules is a function of analyte concentration. The property measured for the reporter beads can be any property which is affected by the analyte interaction with the beads, such as the fluorescence intensity, decay time or spectrum.

(89) Alternatively, the reporter molecules can be absorption indicators, for example the physiological pH indicator N9 (Merck, Germany) immobilized on a substrate bead. Such indicators change their absorption as a function of analyte concentration. Typically the color of the molecules changes (i.e., the wavelength of their absorption maximum changes).

**(90) Absorptive reporter molecules can be used in combination with fluorescent reporter molecules on a substrate bead, and absorptive beads can be used in combination with fluorescent beads.**

(91) The substrate bead function is to allow the detection of an analyte, and optionally its concentration, with optical measurements of single beads. More than one type of reporter bead, i.e., beads with different reporter molecules immobilized thereon, can be used to analyze a given sample, provided that the bead type can be identified. Beads can be identified by various means, including means employing bead size, e.g., light scattering; fluorescent tag(s) attached to the bead which has a different excitation and/or emission wavelength from that of the fluorescent reporter molecule attached to that bead; or by directly identifying the fluorescent molecule attached to the bead. **This allows for detection of more than one analyte at a time.** The substrate bead also functions to immobilize the reporter molecules to prevent their diffusion into the sample stream. The reporter molecules can be on the surface of or within the substrate bead. The beads can be fabricated from a variety of materials and can have any shape, not limited to spherical. Suitable materials include glass, latex, hydrogels, polystyrene and liposomes. The beads can have added surface groups to facilitate attaching reporter molecules, such as carboxyl groups on latex and amino-modified polystyrene.

The Examiner submits that the use of either the multiple absorptive beads or the multiple fluorescent beads meets the limitation of beads having “a first group of label molecules (either absorption or fluorescent) of label molecules on a (third) trapping body and a second group of same label molecules on another (fourth) trapping body”. That is, providing a plurality of **either type of beads** meets the limitation of “using a same label for detecting different target substances” as argued by Applicant. The use of two

or more beads of a type constitutes "using a same label for detecting substances" since each bead has the same label. Weigl also teaches the use of combinations of multiple types of beads. This includes multiple trapping bodies (beads) of each different type (absorption, fluorescent, etc.) - but with each type repeated (i.e. using a same label). Each bead of the repeated type has a "same label for detecting substances".

### ***Conclusion***

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **DWAYNE K. HANDY** whose telephone number is (571)272-1259. The examiner can normally be reached on M-F 11:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dwayne K Handy/  
Examiner, Art Unit 1797

/Jill Warden/  
Supervisory Patent Examiner, Art Unit 1797

May 8, 2010